UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
FARRELL KYSER and JENNIFER KYSER, Plaintiffs, vs. ABBVIE, INC., AND ABBOTT LABORATORIES, INC. Defendants.	COMPLAINT AND JURY DEMAND Civil Action No.: _____

Plaintiffs, by and through undersigned counsel, upon information and belief, at all times hereinafter mentioned, allege as follows:

INTRODUCTION

1. This case involves the prescription drug AndroGel, which is manufactured, sold, distributed and promoted by Defendants as a testosterone replacement therapy.

2. Defendants misrepresented that AndroGel is a safe and effective treatment for hypogonadism or "low testosterone," when, in fact, the drug causes serious medical problems, including life threatening cardiac events, strokes, and thromboembolic events.

3. AndroGel is an exogenous form of the androgen testosterone. It regulates expression of platelet TXA_2 reports in humans, which significantly increases platelet

aggregation. It causes an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes, and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, strokes, and numerous types of cardiovascular injuries.

4. Androgel is delivered transdermally and is applied to the skin in the form of a gel. It is available in either a 1% or 1.62% concentration.

5. Defendants failed to adequately warn physicians about the risks associated with AndroGel and the monitoring required to ensure their patients' safety.

6. Consumers of AndroGel were misled as to the drug's safety and efficacy and, as a result, have suffered injuries, including life-threatening cardiac events, strokes, and thrombolic events.

7. Defendants engaged in aggressive, award-winning direct-to-consumer and physician marketing and advertising for AndroGel. Further, Defendants engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "Low T," which was ultimately designed to sell AndroGel.

8. As a result, diagnoses of Low T have increased exponentially. This has directly related to AndroGel's sales increasing to over $1.37 billion per year.

9. However, consumers of AndroGel were misled as to the drug's safety and efficacy and, as a result, have suffered injuries, including life-threatening cardiac events, strokes, and thromboembolic events.

PARTIES

Plaintiffs Farrell Kyser and Jennifer Kyser

10. Plaintiff Farrell Kyser is a citizen of the United States of America and is a resident of New Brockton, Alabama, located in Coffee County, Alabama.

11. Plaintiff Jennifer Kyser is a citizen of the United States of America and is a resident of new Brockton, Alabama, located in Coffee County, Alabama. At all times relevant to this complaint, Plaintiff Jennifer Kyser was married to Plaintiff Farrell Kyser.

12. Plaintiff Farrell Kyser began using the prescription drug AndroGel as prescribed and directed by his physician on approximately September 11, 2012, and continued to use AndroGel until approximately December 1, 2012.

13. On December 1, 2012, Plaintiff Farrell Kyser, after experiencing increased and worsening shortness of breath and other symptoms, was treated at the emergency room at Medical Center Enterprise, in Coffee County, Alabama. Plaintiff Farrell Kyser was hospitalized at Medical Center Enterprise for approximately four days and was diagnosed with pulmonary thromboembolism.

14. On December 5, 2012, Plaintiff Farrell Kyser was transferred from Medical Center Enterprise to Southeast Alabama Medical Center in Houston County, Alabama, for continued treatment of his injuries. Plaintiff Farrell Kyser was hospitalized and treated at Southeast Alabama Medical Center for approximately four days and was diagnosed with a deep venous thrombosis and a massive pulmonary embolus.

Defendants AbbVie, Inc. and Abbott Laboratories, Inc.

15. Defendant AbbVie, Inc., is a corporation organized and exiting under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

16. Defendant Abbott Laboratories, Inc., is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

17. By way of background, Unimed Pharmaceuticals, Inc., originally developed AndroGel and sought FDA approval in 1999. Before the drug was approved by the FDA in 2000, Solvay Pharmaceuticals, Inc., acquired Unimed Pharmaceuticals, Inc., and subsequently brought AndroGel to market. In 2010, Defendant Abbott Laboratories, Inc., acquired Solvay's pharmaceutical division, which included AndroGel. Then, in 2013, Abbott created AbbVie, a company composed of Abbott's former proprietary pharmaceutical business, which included AndroGel.

18. At all times relevant to this Complaint, the Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related parties, the prescription testosterone replacement therapy drug sold under the name AndroGel throughout the United States, including the State of Alabama.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants and because the amount in controversy exceeds $75,000, exclusive of interest and costs.

20. Venue is proper pursuant 28 U.S.C § 1407 and Case Management Order No. 12 entered by Honorable Matthew F. Kennelly on October 24, 2014, by which this matter may be filed directly in the MDL proceedings in the Northern District of Illinois. Plaintiffs state that but for the Order permitting direct filing into the Northern District of Illinois pursuant to Case Management Order No. 12, Plaintiffs would have filed in the United States District Court for the Middle District of Alabama. Upon completion of pretrial proceedings, Plaintiffs respectfully request that this case be transferred to the United States District Court for the Middle District of Alabama.

GENERAL ALLEGATIONS

21. This action is for damages brought on behalf of Plaintiff Farrell Kyser and Plaintiff Jennifer Kyser. Plaintiff Farrell Kyser was prescribed and supplied with, received, took and applied the prescription drug AndroGel, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, monetary damages for general and special damages sustained and equitable relief in order to enable Plaintiff Farrell Kyser to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

22. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiffs' injuries and damages.

23. At all times herein mentioned, Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling,

inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug AndroGel for the use of application by men, including, but not limited to, Plaintiff Farrell Kyser.

24. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of AndroGel and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiffs herein.

25. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that AndroGel caused the appreciable harm sustained by Plaintiffs. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiffs' injuries as their cause was unknown to Plaintiffs. Plaintiffs were prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug AndroGel is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiffs to discover a potential cause of action.

OVERVIEW

26. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone.

27. The Food and Drug Administration approved AndroGel as "an androgen indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone," specifically "primary hypogonadism" and "hypogonadotrophic hypogonadism."

28. In 1999, when Unimed Pharmaceuticals Inc., one of the Defendants' predecessor companies, asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men."

29. In 2000, when the FDA approved AndroGel, the company announced that the market was "four to five million American men." By 2003, the number increased to "up to 20 million men." However, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001-2011" indicated that many men who receive testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

30. Defendants coordinated a massive advertising campaign designed to convince men that they suffered from low testosterone. Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential AndroGel users, and online media including the unbranded website "IsItLowT.com."

31. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness – all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

32. Defendants' national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to "take the 'Is it Low T' Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low testosterone, including the following: "Have you experienced a recent deterioration in your ability to play sports?"; "Are you falling asleep after dinner?"; "Are you sad and/or grumpy?"; and "Do you have a lack of energy?"

33. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a $40,000 grant to his university. The pharmaceutical company instructed Dr. Morley, "Don't make it too long and make it somewhat sexy." Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morley admits that he has "no trouble calling it a crappy questionnaire" and that it is "not ideal." This is the "Low T Quiz" used on the "IsItLowT" website. Natasha Singer, *Selling that New-Man Feeling*, Nov. 23, 2013 N.Y. TIMES.

34. Since the FDA approved AndroGel, Defendants have also sought to convince primary care physicians that low testosterone levels are widely underdiagnosed and that conditions associated with normal aging could be caused by low testosterone levels.

35. While running their disease awareness campaign, Defendants promote their product AndroGel as an easy to use topical testosterone replacement therapy. Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

36. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

37. What consumers received, however, was not a safe drug, but a product that causes life-threatening problems, including strokes, heart attacks, and thromboembolic events such as deep vein thrombosis and pulmonary embolism.

38. Defendants successfully created a robust and previously nonexistent market for their drug. Defendant Abbott Laboratories spent $80 million promoting AndroGel in 2012. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites that recommend that men have regular checkups with their physicians and five regular tests done, including: cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

39. Defendants' advertising paid off in a return of $1.4 billion in sales during the year 2013, making AndroGel the biggest selling androgen drug in the United States. Sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra*, May 10, 2012, Bloomberg Businessweek, available at: http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

40. In early 2013, Medical Marketing & Media named two AbbVie executives as "the all-star large pharma marketing team of the year" for promotions of AndroGel and unbranded efforts to advance low T. *See* Singer, *Selling That New-man Feeling*, *supra*; *See also*, Larry

Dobrow, A*ll-star large pharma marketing team of the year: Androgel*. Jan. 2, 2013, Medical Marketing & Media, available at: http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article/273242/.

41. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of AndroGel is safe for human use, even though Defendants knew these to be false and had no reasonable grounds to believe them to be true.

42. There have been a number of recent studies suggesting that testosterone in men increases the risk of heart attacks and strokes.

43. For example, in 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

44. In November 2013, a JAMA study entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" indicated that testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

45. On January 29, 2014, a study in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" indicated that testosterone use doubled the risk of heart attacks in men over sixty-five years old and men younger than sixty-five with a previous diagnosis of heart disease.

46. Two days later, on January 31, 2014, the FDA issued a Drug Safety Communication to physicians advising that the FDA was investigating the risk of stroke, heart attack and death in men using testosterone products based on the recent studies suggesting an increased risk of cardiovascular events among men using these products.

47. On April 22, 2014, the European Medicines Agency announced that in light of the recent studies regarding the increased risk of cardiovascular events in patients using testosterone products, its Pharmacovigilance Risk Assessment Committee would be reviewing all data on the benefit-risk balance of testosterone-containing medicines to determine whether the marketing authorizations for these products should be maintained, varied, suspended or withdrawn across the European Union.

48. Additional studies and medical evidence further indicate that the use of testosterone in men increases hematocrit, hemoglobin, and estradiol, thereby increasing the risk of thromboembolic events, such as deep vein thrombosis and pulmonary embolism.

49. Defendants knew or in the exercise of reasonable care should have known that their product, AndroGel, was defectively designed, unreasonably dangerous in normal use, and highly likely to cause injury or death, but failed to provide adequate warnings about these known risks.

FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

50. The Food and Drug Administration approved AndroGel 1% on February 28, 2000, for the treatment of adult males who have low or no testosterone (AndroGel 1.62% was approved in April 2011). After FDA approval, AndroGel was widely and aggressively advertised and marketed by Defendants as a safe and effective testosterone replacement therapy.

51. Primary hypogonadism is described in the AndroGel label as “testicular failure due to conditions such as cryptorchidism, bilateral torsion, orthitis, vanishing testis syndrome, orchiectomy, Klinefelter’s syndrome, chemotherapy, or toxic change from alcohol or heavy metals.”

52. Hypogonadotrophic hypogonadism is described in the AndroGel label as "idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation."

53. AndroGel is hydroalcoholic gel containing testosterone in either 1% or 1.62%, applied to the chest, arms or stomach and enters the body through transdermal absorption. The AndroGel 1.62% product also contains isopropyl myristate as an ointment and ethanol for absorption enhancement.

54. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

55. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

56. In men, testosterone levels normally begin a gradual decline after the age of thirty.

57. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. As a result, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.

58. AndroGel may produce undesirable side effects in patients who use the drug, including, but not limited to, myocardial infarction, stroke, thromboembolic events, and death.

59. In some patient populations, AndroGel use may increase the incidence of myocardial infarctions and death by over 500%.

60. AndroGel has also been linked to several severe and life changing medical disorders in both users and those who come into physical contact with users or with the

unwashed clothes of someone who applied AndroGel. Patients taking AndroGel may experience enlarged prostates and increased serum prostate-specific antigen levels.

61. Secondary exposure to AndroGel can cause side effects in others. In 2009, the FDA issued a black box warning for AndroGel prescriptions, advising patients of reported virilization of children who were secondarily exposed to the gel. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with AndroGel.

62. Defendants' marketing strategy beginning in 2000 has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.

63. Defendants successfully marketed AndroGel by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy, are actually attributable to "Low-T."

64. Defendants' advertising program sought to create the perception, believed by consumers and the medical community, that the use of AndroGel was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives. Defendants had no reasonable grounds to believe these claims were true and knew or should have known these claims were false.

65. Defendants' advertising program sought to create the perception, believed by consumers and the medical community, that AndroGel was a safe and effective method of

alleviating symptoms associated with "Low-T" in men who had not been diagnosed with either primary hypogonadism or hypogonadotrophic hypogonadism, thus constituting off-label promotion in violation of federal law.

66. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using AndroGel. Defendants deceived potential AndroGel users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

67. Defendants concealed material relevant information from potential AndroGel users and minimized user and prescriber concerns regarding the safety of AndroGel.

68. In particular, in the warnings Defendants provide in their television commercials, online marketing and print advertisements, Defendants fail to mention any potential cardiac, stroke, or thromboembolic side effects and falsely represent that Defendants adequately tested AndroGel for all likely side effects.

69. AndroGel's prescribing information and medication guide contained within the package materials do not warn against stroke, pulmonary embolism, deep vein thrombosis, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure or any thromboembolic event.

70. On June 19, 2014, in response to the post-market reports of venous blood clots in testosterone users, the FDA announced that it was requiring manufacturers of testosterone to include a general warning in the drug labeling of all approved testosterone medications about the risk of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

71. As a result of this mandate by the FDA, on June 21, 2014, the Defendants updated the prescribing information to provide the general warning required by FDA regarding DVT and PE and also updated the medication guide for AndroGel to include the significant risk of PE as follows: "Blood clots in the legs or lungs. Signs and symptoms of a blood clot in your leg can include leg pain, swelling or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain." The new prescribing information and the medication guide contained within the package materials, however, still lacks any warning about the risk of elevated estradiol levels, the need to screen for underlying clotting traits, or risks of strokes or cardiovascular injuries.

72. As a result of Defendants' advertising, marketing, and representations about its product, men in the United States pervasively seek out prescriptions for AndroGel. If Plaintiff Farrell Kyser had known the risks and dangers associated with AndroGel, he would not have taken AndroGel and consequently would not have been subject to its serious side effects.

SPECIFIC FACTUAL ALLEGATIONS

73. Plaintiff Farrell Kyser was prescribed AndroGel and used it as directed from approximately September 11, 2012, to December 1, 2012.

74. Plaintiff Farrell Kyser was 63 years old when he was prescribed and used AngroGel for symptoms he attributed to low testosterone.

75. Plaintiff Farrell Kyser had no prior history of pulmonary embolism prior to taking testosterone. In keeping with his active lifestyle, Plaintiff Farrell Kyser agreed to initiate testosterone treatment.

76. Plaintiff Farrell Kyser and his physician relied on claims made by Defendants that testosterone had been clinically shown to safely and effectively raise testosterone levels.

77. Plaintiff Farrell Kyser was hospitalized and diagnosed with a deep vein thrombosis and a massive pulmonary embolus in December 2012. As a result, he must undergo long-term supplemental oxygen therapy and take anticoagulation therapy daily.

78. As a direct and proximate result of using AndroGel, Plaintiff Farrell Kyser suffered the injuries described above.

79. Prior to and at the time of Plaintiff Farrell Kyser's use of AndroGel, Defendants knew or should have known that the use of AndroGel created a significantly increased risk of serious personal injury, including stroke, heart attack, blood clots, and even death, and that such use was unreasonably dangerous to consumers such as Plaintiff Farrell Kyser.

80. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of AndroGel, Defendants failed to adequately warn Plaintiff Farrell Kyser and/or his health care providers of these risks before he used the product.

81. Had Defendants properly disclosed the risks associated with AndroGel and other testosterone products, Plaintiff Farrell Kyser would have avoided the risk of deep vein thrombosis and pulmonary emboli by not using AndroGel and/or testosterone at all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs were adversely affecting his health.

82. As a direct and proximate result of Plaintiff Farrell Kyser's use of AndroGel, Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug testosterone, Plaintiff Farrell Kyser suffered severe and permanent physical and emotional injuries, including, but not limited to, a deep vein thrombosis and massive pulmonary embolus, which may have caused permanent effects and may continue in the future to cause him physical effects and damages.

83. Further, as a direct and proximate result of Plaintiff Farrell Kyser's use of AndroGel, Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug testosterone, Plaintiff Farrell Kyser has suffered significant mental anguish and emotional distress and will continue to suffer physical limitations, pain, injury, damages, harm and mental and emotional distress in the future.

84. Plaintiff Farrell Kyser has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of his use of AndroGel and Defendants' conduct as described herein.

FIRST CAUSE OF ACTION

Alabama Extended Manufacturer's Liability Doctrine Manufacturing Defect

85. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

86. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of AndroGel.

87. The AndroGel manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was expected to and did reach the consumer without any alterations or changes.

88. The AndroGel manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left the hands of Defendants, in that they deviated from product specification such that they were unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.

89. As a direct and proximate result of Plaintiff Farrell Kyser's use of AndroGel as manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, Plaintiff Farrell Kyser has suffered serious physical injury, harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

90. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages. Plaintiffs reserve the right to present evidence justifying the imposition of punitive damages after a hearing before the court and in accordance with Ala. Code §6-11-20 et seq.

WHEREFORE, Plaintiffs pray for relief as follows: compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $75,000; medical expenses and other economic damages in an amount to be determined at trial of this action; attorneys' fees, expenses, and costs of this action; compensation for mental anguish and pain and suffering; and such further relief as this Court deems necessary, just, and proper.

SECOND CAUSE OF ACTION

Alabama Extended Manufacturer's Liability Doctrine Design Defect

91. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

92. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of AndroGel.

93. The AndroGel manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was expected to and did reach the consumer without any alterations or changes.

94. The AndroGel manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or they were more dangerous than an ordinary customer would expect.

95. The foreseeable risks associated with the design or formulation of AndroGel include, but are not limited to, the fact that the design or formulation of AndroGel is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

96. As a direct and proximate result of Plaintiff Farrell Kyser's use of AndroGel as manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, Plaintiff Farrell Kyser has suffered serious physical injuries, economic and non-economic damages, including pain and suffering.

97. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages. Plaintiffs reserve the right to present evidence justifying the imposition of punitive damages after a hearing before the court and in accordance with Ala. Code § 6-11-20 et seq.

WHEREFORE, Plaintiffs pray for relief as follows: compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $75,000; medical expenses and other economic damages in an amount to be

determined at trial of this action; attorneys' fees, expenses, and costs of this action; compensation for mental anguish, pain and suffering; and such other relief as this Court deems necessary, just, and proper.

THIRD CAUSE OF ACTION

Strict Product Liability – Failure to Warn

98. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

99. The AndroGel manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions, because Defendants knew or should have known that the product was unreasonably dangerous to consumers in that it created a significant risk of serious bodily harm and death to reasonably foreseeable consumers, such as Plaintiff Farrell Kyser, and Defendants failed to adequately warn or instruct consumers and/or their health care providers of such risks.

100. The AndroGel manufactured and/or supplied by Defendants was also defective due to inadequate post-marketing warnings or instructions, because, after Defendants knew or should have known of the significant risk of serious bodily harm and death from the use of AndroGel, Defendants failed to provide adequate warnings to consumers and/or health care providers of the product, knowing the product could cause serious injury and death.

101. As a direct and proximate result of Plaintiff Farrell Kyser's reasonably anticipated use of AndroGel as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff Farrell Kyser suffered serious personal injury, economic and non-economic damages, and will continued to suffer such harm, damages and losses in the future.

102. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiffs' rights, so as to warrant the imposition of punitive damages. Plaintiffs reserve the right to present evidence justifying the imposition of punitive damages after a hearing before the court and in accordance with Ala. Code § 6-11-20 et seq.

WHEREFORE, Plaintiffs pray for relief as follows: compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $75,000; medical expenses and other economic damages in an amount to be determined at trial of this action; attorneys' fees, expenses, and costs of this action; compensation for mental anguish, pain and suffering; and such further relief as this Court deems necessary, just, and proper.

FOURTH CAUSE OF ACTION

Negligence

103. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

104. Defendants had a duty to exercise reasonable care in the manufacture, design, sale, distribution, supply, marketing, and/or placement of AndroGel into the stream of commerce, including a duty to ensure that their product did not pose a significant increased risk of bodily harm and adverse events, such as stroke, heart attack, thromboembolism, and death, and a duty to adequately warn of the risks and dangers of AndroGel.

105. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion, and distribution of AndroGel into interstate commerce in that Defendants knew, or should have

known, that the product caused such significant bodily harm or death and was not safe for use by consumers.

106. Defendants also failed to exercise reasonable care in the labeling of AndroGel and failed to provide to consumers and/or their health care providers adequate warnings of the increased risk of bodily injury or death due to the use of AndroGel.

107. Despite the fact that Defendants knew or should have known that AndroGel caused unreasonable, dangerous side effects, as described herein, Defendants continued to manufacture and market AndroGel for use by consumers including Plaintiff Farrell Kyser, even though there were safer alternative methods of treating loss of energy, loss of libido, erectile dysfunction, depression, loss of muscle mass, and other symptoms and conditions, which Defendants claim to be caused by low testosterone.

108. Defendants knew or should have known that consumers, such as Plaintiff Farrell Kyser, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

109. As a direct and proximate result of Defendants' negligence, Plaintiff Farrell Kyser suffered personal injury, economic and non-economic damages and will continue to suffer such harm, damages, and economic loss in the future.

110. Defendants' conduct as alleged in this Complaint, including but not limited to their failure to adequately test AndroGel and to provide adequate warnings and their continued manufacture, sale and marketing of the products when they knew or should have known of the serious health risks the product created, evidences malicious actions, aggravated or egregious fraud, and/or intentional disregard of the rights of Plaintiffs so as to warrant the imposition of punitive damages. Plaintiffs reserve the right to preserve evidence justifying the imposition of

punitive damages after a hearing before the court and in accordance with Ala. Code §6-11-20 et seq.

WHEREFORE, Plaintiffs pray for relief as follows: compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $75,000; medical expenses and other economic damages in an amount to be determined at trial of this action; attorneys' fees, expenses, and costs of this action; compensation for mental anguish, pain and suffering; and such further relief as this Court deems necessary, just, and proper.

FIFTH CAUSE OF ACTION

Negligent Misrepresentation and/or Fraud

111. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

112. Defendants are the manufacturers, designers, distributors, sellers or suppliers of AndroGel and, while engaged in the course of such business, made representations to Plaintiff Farrell Kyser and his physician regarding the character and/or quality of AndroGel for guidance in their decision to select AndroGel for Plaintiff Farrell Kyser's use.

113. Specifically, Defendants represented that their product was just as safe, and just as effective or more effective, than other testosterone replacement drugs on the market.

114. Defendants' representations regarding the character and quality of AndroGel were untrue.

115. Defendants had or should have had knowledge and information based upon studies, published reports and clinical experience that its product, AndroGel, created an unreasonable risk of serious bodily injury and death to consumers.

116. In order to avoid losses and sustain profits in their sales to consumers, Defendants negligently and/or intentionally misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised AndroGel as safe and effective.

117. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to their intended recipients, including Plaintiff Farrell Kyser and his physician.

118. Plaintiff Farrell Kyser and his physician reasonably relied to his detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff Farrell Kyser reasonably relied upon Defendants' representations to him and/or his health care providers that AndroGel was just as safe an effective as other types of testosterone replacements for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

119. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiff Farrell Kyser suffered personal injury, economic and non-economic damages and will continue to suffer such harm, damages, and economic loss.

120. Defendants' action and omission as alleged and identified in this Complaint were oppressive, fraudulent, or malicious, so as to warrant the imposition of punitive damages. Plaintiffs reserve the right to present evidence justifying the imposition of punitive damages after a hearing before the court and in accordance with Ala. Code § 6-11-20 et seq.

WHEREFORE, Plaintiffs pray for relief as follows: compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in

excess of $75,000; medical expenses and other economic damages in an amount to be determined at trial of this action; attorneys' fees, expenses, and costs of this action; compensation for mental anguish, pain and suffering; and such further relief as this Court deems necessary, just, and proper.

SIXTH CAUSE OF ACTION

Breach of Express Warranty

121. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

122. Defendants expressly warranted to Plaintiff Farrell Kyser and his physicians, by and through statements made by Defendants or their authorized agents or sales representative, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that AndroGel was safe, effective, fit and proper for its intended use.

123. Plaintiff Farrell Kyser purchased and used AndroGel, and Plaintiff Farrell Kyser's physician prescribed AndroGel, relying on the skill, judgment, representations, and express warranties of Defendants.

124. Contrary to Defendants' express warranties, Defendants' AndroGel did not conform to these express representations and warranties, because AndroGel caused serious injury to consumer such as Plaintiff Farrell Kyser who used the product when taken in the recommended dosages.

125. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff Farrell Kyser suffered personal injury, economic and non-economic damages and will continue to suffer such harm, damages, and economic loss in the future.

WHEREFORE, Plaintiffs pray for relief as follows: compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $75,000; medical expenses and other economic damages in an amount to be determined at trial of this action; attorneys' fees, expenses, and costs of this action; compensation for mental anguish, pain and suffering; and such further relief as this Court deems necessary, just, and proper.

SEVENTH CAUSE OF ACTION

Breach of Implied Warranty

126. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

127. At the time Defendants manufactured, marketed, sold, and distributed AndroGel, Defendants knew of the use for which AndroGel was intended, and Defendants impliedly warranted to Plaintiff Farrell Kyser and to his physicians that AndroGel was merchantable quality, safe, and fit for the use for which it was intended.

128. Plaintiff Farrell Kyser was and is unskilled in the research, design, and manufacture of AndroGel and reasonably relied on the skill, judgment and implied warranty of Defendants in deciding to use AndroGel.

129. Contrary to their implied warranty, Defendants' product AndroGel was not of merchantable quality, safe, or fit for its intended use, because it was unreasonably dangerous as described herein.

130. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Farrell Kyser suffered personal injury, economic and non-economic damages and will continue to suffer such harm, damages, and economic loss in the future.

WHEREFORE, Plaintiffs pray for relief as follows: compensatory and punitive damages in excess of the jurisdictional amount, including but not limited to non-economic damages in excess of $75,000; medical expenses and other economic damages in an amount to be determined at trial of this action; attorneys' fees, expenses, and costs of this action; compensation for pain and suffering; and such further relief as this Court deems necessary, just, and proper.

EIGHTH CAUSE OF ACTION

Intentional and Wanton Conduct and Request for Punitive Damages

131. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

132. At all times relevant herein, Defendants knew or should have known that AndroGel was inherently dangerous.

133. Despite their knowledge, Defendants continued to aggressively market AndroGel to consumers, including Plaintiff Farrell Kyser, without disclosing its dangerous side effects when there existed safer alternative products.

134. Despite Defendants' knowledge of AndroGel's defective and unreasonably dangerous nature, Defendants continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff Farrell Kyser, in conscious disregard of the foreseeable harm caused by AndroGel.

135. The Defendants' conduct was intentional and/or wanton.

136. The Defendants' conduct as described above, including, but not limited to, their failure to adequately test their product, to provide adequate warnings, and their continued

manufacture, sale, and marketing of their products when they knew or should have known of the serious health risks created, evidences a flagrant disregard for human life as to warrant the imposition of punitive damages as the acts or omissions were committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff Farrell Kyser. Plaintiffs reserve the right to present evidence justifying the imposition of punitive damages after a hearing before the court and in accordance with Ala. Code § 6-11-20 et seq.

WHEREFORE, Plaintiffs pray for relief as follows: compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $75,000; medical expenses and other economic damages in an amount to be determined at trial of this action; attorneys' fees, expenses, and costs of this action; compensation for mental anguish, pain and suffering; and such further relief as this Court deems necessary, just, and proper.

NINTH CAUSE OF ACTION

Loss of Consortium – Jennifer Kyser

137. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

138. As a result of the foregoing acts and omissions, and the resulting injuries, including, but not limited to, personal injuries, medical expenses, and pain and suffering sustained by Plaintiff Farrell Kyser, Plaintiff Jennifer Kyser has suffered the loss of companionship, society, services and consortium of her husband.

WHEREFORE, Plaintiffs pray for relief as follows: compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in

excess of $75,000; medical expenses and other economic damages in an amount to be determined at trial of this action; attorneys' fees, expenses, and costs of this action; compensation for mental anguish, pain and suffering; and such further relief as this Court deems necessary, just, and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue applicable in this case;
2. Awarding compensatory damages in excess of the jurisdictional minimum of this Court to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, medical expenses, health care costs, and medical monitoring, together with interest and costs as provided by law;
3. Awarding all applicable statutory damages of the state whose laws govern this action;
4. Awarding Plaintiffs reasonable attorneys' fees;
5. Awarding Plaintiffs the costs of these proceedings;
6. Plaintiffs further reserve the right to amend their Complaint to allege claims for and request punitive and/or exemplary damages in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future; and
7. For such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all issues.

Dated: November 20, 2014

Respectfully submitted,

THE COCHRAN FIRM-DOTHAN, P.C.

/s/ Angela J. Mason
Angela J. Mason
J. Farrest Taylor
E. Leanne Richardson
111 East Main Street
Dothan, AL 36301
334-673-1555 Phone
334-699-7229 Fax
angelamason@cochranfirm.com
farresttaylor@cochranfirm.com
lrichardson@cochranfirm.com